K060145

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APPENDIX I
SUMMARY OF SAFETY AND EFFECTIVENESS
For
KMI Cement Restrictor

OCT 5 - 2006

1. **Submitter:**
Kinetikos Medical, Inc.
6005 Hidden Valley Rd. Suite 180
Carlsbad, CA 92011

Contact Person:
John G. Spampinato, V. P., Q.A
Kinetikos Medical, Inc.
6005 Hidden Valley Road Suite 180
Carlsbad, CA 92011
(760) 448 1706 FAX (760) 448 1739

Date Prepared: May 25, 2006

2. **Trade Name:** KMI Cement Restrictor
Common Name: Bone Plug
Classification Name: Cement Obturator
Device Product Code: LZN (878.3300)

3. **Predicate or legally marketed devices which are substantially equivalent**
-ImproVise Absorabale Cement Flow Restrictor (K011943)

4. **Description of Device**
The KMI Cement Restrictor Implant is a flexible, bio-resorbable restrictor designed to provide a quick and effective method of plugging the intramedulalry canal with an easy-to-place absorbable bone plug. Based on the size of the canal and reamer used to form the channel, the appropriate size cement restrictor is selected and is guided into the canal to the desired depth. The KMI Cement Restrictors are malleable to take on the irregular shape of the canal, effectively sealing them at the desired friction-fit position. There are a variety of sizes and shapes offered, including cylindrical and cube versions. Each device can be custom shaped either by manual manipulation, by using a scalpel at the time of surgery, or by press-fitting into the canal.
Materials: L,D-L Lactic Acid Polymer
Shelf Life: This product will be labeled with a shelf life of two (2) years

5. **Intended Use** The KMI Cement Restrictor Implant is intended to be implanted inside the intramedullary canal for use as an absorbable bone cement flow restrictor plug. The safety and effectiveness of this device for use in the spine have not been established.

Use of this implant is <u>contraindicated</u> for use in patients with the following conditions:

- Active local infection / any evidence of infection
- Allergic reaction to foreign bodies
- Poor or insufficient bone stock
- The presence of any clinical or functional abnormalities that would preclude the potential of achieving a good result for the patient
- Other conditions that may place the patient at risk (physiologically)
- Or for spinal applications

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Kinetikos Medical Incorporated
c/o Mr. John Spampinato
6005 Hidden Valley Road
Carlsbad, California 92011

OCT 5 - 2006

Re: K061465
KMI Cement Restrictor
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: JDK
Dated: August 29, 2006
Received: September 13, 2006

Dear Mr. Spampinato:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA) application. You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

WARNING: THIS DEVICE IS NOT INTENDED FOR ANY SPINAL INDICATIONS.

THE SAFETY AND EFFECTIVENESS OF THIS DEVICE WHEN IMPLANTED IN THE SPINE HAVE NOT BEEN ESTABLISHED.

These warnings must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

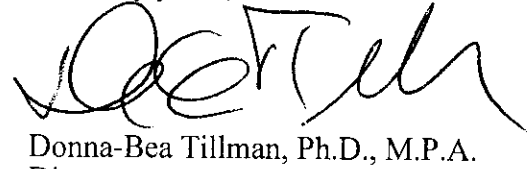
The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices an Radiological Health

Enclosure

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APPENDIX IX

Indications for Use

510(k) Number (if known):

Device Name: KMI Cement Restrictor Implant

Indications For Use:
The KMI Cement Restrictor Implant is intended to be implanted inside the intramedullary canal for use as an absorbable bone cement flow restrictor plug.

The safety and effectiveness of this device for use in the spine have not been established.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Catherine Brenner

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)
Division of General, Restorative,
and Neurological Devices

510(k) Number K061465